

# URGENT DRUG INFORMATION

February 13, 2001

Dear Health Care Provider:

We are writing to inform you of three reported incidents of product tampering. Specifically, the flip caps from the tops of eight vials from different lots of EPOGEN® (Epoetin alfa) and NEUPOGEN® (Filgrastim) were removed and the contents of the vials extracted. The contents were replaced with varying amounts of an aqueous solution and the vials were resealed in an apparent effort to conceal product theft.

In all reported instances, the product was not used because a crusty white material was readily visible below the caps, or because particulate matter was observed in the solution. Although the replacement solution has thus far been shown to be non-toxic, the sterility of these vials was compromised. Therefore, a possibility exists that the solution introduced into the vials could pose a safety risk, especially if administered to immune compromised patients. The vials involved in these reports were from EPOGEN lots P000839, P000841; and NEUPOGEN lots (300 mcg) P000928, P000698.

As stated in the package inserts for EPOGEN and NEUPOGEN and all parenteral drug products, vial contents should be inspected visually for particulate matter and discoloration prior to administration.

**If you see any evidence of tampering of EPOGEN or NEUPOGEN vials, e.g., vials that appear to have been opened, have white crusty deposits around the stopper, appear to contain discolored or cloudy fluid, particulate matter, volumes less or greater than expected, or if the labels appear worn, DO NOT USE the vials and call 1-800-772-6436 at Amgen.**

Please convey this information to your staff who administer these products and to your patients who self-administer these products. You should instruct them on what to look for and what to do in the event they find a suspect vial.

Amgen and the United States Food and Drug Administration are investigating this matter. Amgen is taking all possible steps to protect the quality and integrity of its products. Thank you for your attention to this urgent matter.

Sincerely,



Martha E. Vincent, Ph.D.  
VP Corporate Professional Services